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300.1012

UNITED STATES PATENT AND TRADEMARK

TECH CENTER 1600/2900

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Re: Application of: Xiu Xiu Cheng, et al.  
Serial No.: 09/705,625  
Filed: November 3, 2000  
For: **Methods for Treating Diabetes Via  
Administration Of Controlled Release  
Metformin**  
Examiner: T. Ware Art Unit: 1615

INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents  
Washington, D.C. 20231

February 28, 2003

Sir:

In accordance with Applicant's duty of disclosure under 37 C.F.R. §1.56 and the provisions of 37 C.F.R. §§ 1.97 and 1.98, Applicants hereby make of record the documents listed on the accompanying Form PTO-1449 for consideration by the Examiner in connection with the examination of the above-identified patent application.

Applicants note that reference AM is being submitted in an envelope labeled "PROPRIETARY MATERIAL NOT OPEN TO PUBLIC. TO BE OPENED ONLY BY EXAMINER OR OTHER AUTHORIZED U.S. PATENT AND TRADEMARK OFFICE EMPLOYEE." as this material in the envelope is considered proprietary and is being submitted for consideration under MPEP §724 (8<sup>th</sup> Edition).

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The biostudy (which resulted in the data submitted as reference AM) was performed using formulations prepared in accordance with U.S. Patent No. 6,099,859. It is noted that the exemplified formulations did not provide a  $T_{\max}$  between 8-12 hours except when the formulation prepared in accordance with Example 3 was administered at dinner. As set forth in the accompanying biostudy data, the mean  $T_{\max}$  values for the Examples of the '859 were as follows: Example 1 (fasting) 4.67 hours (*See, e.g.*, pages 1 and 3 of the biostudy); Example 2 (fasting) 4.33 hours (*See, e.g.*, pages 10 and 12 of the biostudy); Example 2 (fed a.m.) 6.80 hours (*See, e.g.*, pages 13, 14 and 16 of the biostudy); Example 3 (fed a.m.) 6.67 hours (*See, e.g.*, pages 4 and 6 the biostudy); Example 3 (Fed p.m.) 9.67 hours (*See, e.g.*, pages 17 and 20 of the biostudy). Therefore, the only instance that the  $T_{\max}$  was between 8-12 hours was Example 3 fed in the P.M. (at dinner).

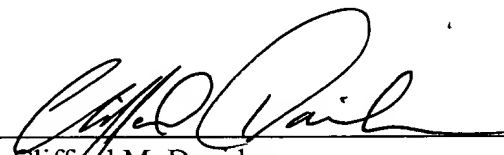
In addition, pages 2, 5, 11, 15, 19 of the biostudy data includes plasma concentration v. time graphs and data for formulations prepared in accordance with Examples 1(fasting), 3 (fed), 2 (fasting), 2 (fed), and 3 (fed), respectively, of U.S. Patent No. 6,099,859; pages 8 and 9 of the biostudy data include plasma concentration v. time graphs and data for formulations prepared in accordance with Example 2 (fasting and fed) and Example 3 (fed a.m. and p.m.) of U.S. Patent No. 6,099,859; and pages 7 and 18 include plasma concentration v. time graphs and data for formulations prepared in accordance with Example 3 (fed a.m. and p.m.) of U.S. Patent No. 6,099,859.

This Information Disclosure Statement is being filed after a First Office Action but before a Final Office Action or Notice of Allowance. Pursuant to 37 C.F.R. § 1.98(c), a check for \$180.00 is enclosed to cover the required fee. However, if it is determined that any fee is due, the Examiner is authorized to charge said fee to Attorney Deposit Account No. 50-0552.

Respectfully submitted,

DAVIDSON, DAVIDSON & KAPPEL, LLC

By: \_\_\_\_\_

  
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FORM PTO-1449  
(REV. 7-80)

U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICE

ATTY. DOCKET NO.:  
300.1012

SERIAL NO.:  
09/705,625

**LIST OF PRIOR ART CITED BY APPLICANT**

(Use several sheets if necessary)

APPLICANT(S): Xiu Xiu CHENG, et al.

FILING DATE:  
November 3, 2000

GROUP:  
1615

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	AA	6	4	7	5	5	2	1	11/05/2002	Timmins et al.	424	469	Sep. 16, 1999
	AB												
	AC												
	AD												
	AE												
	AF												
	AG												

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO
	AH													
	AI													
	AJ													
	AK													
	AL													

OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

	AM	Andrx Pilot Biostudy Data (20 pages)
	AN	
	AO	
	AP	
	AQ	
	AR	
	AS	

EXAMINER

DATE CONSIDERED

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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ASSISTANT COMMISSIONER FOR PATENTS  
Washington, DC 20231

In re application: **Xiu Xiu Cheng, et al.**

Serial No.: **09/705,625**

Filed: **November 3, 2000**

For: **METHODS FOR TREATING DIABETES VIA ADMINISTRATION OF CONTROLLED RELEASE METFORMIN**

RECEIVED  
Docket No.: 300.1012  
Date: February 28, 2003

MAR 14 2003

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Sir:

Transmitted herewith is an **Information Disclosure Statement** in the above-identified application.

- ☐ Small entity status under 37 C.F.R. 1.9 and 1.27 has been previously established.  
☐ Applicants assert small entity status under 37 C.F.R. 1.9 and 1.27.  
☒ No fee for additional claims is required.  
☐ A filing fee for additional claims calculated as shown below, is required:

FOR:	(Col. 1)		(Col. 2)		SMALL ENTITY		OR	LARGE ENTITY	
	REMAINING	HIGHEST	PREVIOUSLY	PRESENT	RATE	FEE		RATE	FEE
	AFTER		PAID FOR	EXTRA					
TOTAL CLAIMS	* Minus**	=		x0\$ 9	\$		x	\$ 18	\$
INDEP. CLAIMS	* Minus***	=		x0\$ 40	\$		x	\$ 80	\$
[ ] FIRST PRESENTATION OF MULTIPLE DEP. CLAIMS					\$		+	\$ 270	\$

TOTAL: \$            OR TOTAL: \$           

- ☒ Also transmitted herewith are:

☐ Petition for extension under 37 C.F.R. 1.136

☒ Other: **Form PTO 1449 and accompanying reference; and Material Submitted for consideration under MPEP § 724**

- ☒ Check(s) in the amount of **\$180.00** is/are attached to cover:

☐ Filing fee for additional claims under 37 C.F.R. 1.16

☐ Petition fee for extension under 37 C.F.R. 1.136

☒ Other: **Fee for submission of Information Disclosure Statement**

- ☒ The Assistant Commissioner is hereby authorized to charge payment of the following fees associated with this communication or credit any overpayment to Deposit Account No. 50-0552.

☒ Any filing fee under 37 C.F.R. 1.16 for the presentation of additional claims which are not paid by check submitted herewith.

☒ Any patent application processing fees under 37 C.F.R. 1.17.

☒ Any petition fees for extension under 37 C.F.R. 1.136 which are not paid by check submitted herewith, and it is hereby requested that this be a petition for an automatic extension of time under 37 CFR 1.136.

  
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